



General Assembly

February Session, 2006

Raised Bill No. 5246

LCO No. 1000

01000_____PH_

Referred to Committee on Public Health

Introduced by:
(PH)

***AN ACT ENSURING THE SAFETY OF MEDICINE THROUGH THE USE
OF AUTOMATED DRUG DELIVERY SYSTEMS.***

Be it enacted by the Senate and House of Representatives in General
Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2006*) As used in sections 1 to 3,
2 inclusive, of this act:

3 (1) "Automated drug delivery system" means a mechanical system
4 that performs operations or activities, other than compounding or
5 administration, relative to the storage, dispensing or distribution of
6 drugs;

7 (2) "Drug" means a legend drug, as defined in section 20-571 of the
8 general statutes, or a controlled drug, as defined in section 21a-240 of
9 the general statutes;

10 (3) "Health care facility or institution" means a health care facility or
11 institution licensed by the Department of Public Health pursuant to
12 chapter 368v of the general statutes;

13 (4) "Pharmacy" means a pharmacy licensed pursuant to chapter 400j
14 of the general statutes;

15 (5) "Pharmacist" means an individual who is licensed to practice
16 pharmacy pursuant to chapter 400j of the general statutes;

17 (6) "Pharmacy intern" means an individual who is registered
18 pursuant to section 20-598 of the general statutes; and

19 (7) "Pharmacy technician" means an individual who is registered or
20 certified with the Department of Public Health and qualified in
21 accordance with section 20-598a of the general statutes.

22 Sec. 2. (NEW) (*Effective October 1, 2006*) (a) A health care facility or
23 institution may provide, in accordance with this section, routine and
24 emergency pharmacy services to its patients through the use of an
25 automated drug delivery system operated by a pharmacy in
26 accordance with the provisions of section 3 of this act.

27 (b) Any such health care facility or institution shall ensure that all of
28 the following requirements are met:

29 (1) Each health care facility or institution and the pharmacy that
30 operates an automated drug delivery system on behalf of such facility
31 or institution develops and implements written policies and
32 procedures, in accordance with this section and section 3 of this act,
33 and to ensure safety, accuracy, accountability, security, patient
34 confidentiality and maintenance of the quality, potency and purity of
35 stored drugs. Such policies and procedures shall (A) define access to
36 the automated drug delivery system, (B) limit access to equipment and
37 drugs to personnel authorized by law to administer drugs, and (C) be
38 maintained at both the pharmacy operating the automated drug
39 delivery system and the health care facility or institution where the
40 automated drug delivery system is being used.

41 (2) Any drug removed from the automated drug delivery system for
42 administration to a patient is in properly labeled units of
43 administration containers or packages.

44 (3) A pharmacist (A) reviews and approves all orders prior to a

45 drug being removed from the automated drug delivery system for
46 administration to a patient, and (B) reviews the authorized prescriber's
47 order and the patient's profile for potential contraindications and
48 adverse drug reactions.

49 (4) The pharmacy providing pharmacy services to the health care
50 facility or institution controls access to the drugs stored in the
51 automated drug delivery system.

52 (5) Access to the automated drug delivery system is controlled and
53 tracked using an identification or password system or biosensor.

54 (6) The automated drug delivery system makes a complete and
55 accurate record of all transactions that includes all users accessing the
56 system and all drugs added to or removed from the system.

57 (7) The automated drug delivery system is capable of collecting,
58 controlling and maintaining all transaction information to accurately
59 track the movement of drugs into and out of the system for security,
60 accuracy and accountability.

61 (8) All transaction information collected by the automated drug
62 delivery system is made readily available in a written format for
63 review and inspection by individuals authorized to review and inspect
64 the system and is maintained in the health care facility or institution
65 for a minimum of three years.

66 (9) After a pharmacist reviews and approves an authorized
67 prescriber's order, access by individuals authorized to use the
68 automated drug delivery system, in accordance with this subsection
69 and the policies adopted pursuant to subdivision (1) of this subsection,
70 is limited to the prescribed drug authorized by the pharmacist and
71 specific to the patient. If the authorized prescriber's order requires a
72 dosage variation of the same drug, access by authorized personnel is
73 limited to the drug ordered for that scheduled time of administration.

74 (c) When used as an emergency pharmaceutical supplies container,

75 drugs removed from the automated drug delivery system shall be
76 limited to the following:

77 (1) A new drug order given by an authorized prescriber for a patient
78 of the facility for administration prior to the next scheduled delivery
79 from the pharmacy, or seventy-two hours, whichever is less. Such
80 drugs shall be retrieved only upon authorization by a pharmacist and
81 after the pharmacist has reviewed the authorized prescriber's order
82 and the patient's profile for potential contraindications and adverse
83 drug reactions.

84 (2) Drugs that an authorized prescriber has ordered for a patient on
85 an as-needed basis, if the utilization and retrieval of those drugs are
86 subject to ongoing review by a pharmacist.

87 (3) Drugs designed by the patient care policy committee or
88 pharmaceutical service committee of the health care facility or
89 institution as emergency drugs or acute onset drugs. Such drugs may
90 be retrieved from an automated drug delivery system pursuant to the
91 order of an authorized prescriber for emergency or immediate
92 administration to a patient of the facility. Not later than forty-eight
93 hours after retrieving drugs from the system pursuant to this
94 subdivision, a pharmacist shall review the retrieval.

95 (d) Only a pharmacist may stock an automated drug delivery
96 system. If the automated drug delivery system uses removable pockets
97 or drawers, or similar technology, the system may be stocked outside
98 of the health care facility or institution and then delivered to the
99 facility or institution, provided all of the following conditions are met:

100 (1) A pharmacist, pharmacy intern or pharmacy technician places
101 drugs into the removable pockets or drawers, provided a pharmacy
102 intern or pharmacy technician shall complete such task under the
103 direct supervision of a pharmacist.

104 (2) The removable pockets or drawers are transported between the

105 pharmacy and the health care facility or institution in a secure tamper-
106 evident container.

107 (3) The health care facility or institution, in conjunction with the
108 pharmacy, has developed and implemented policies and procedures to
109 ensure that the pockets or drawers are properly placed into the
110 automated drug delivery system.

111 Sec. 3. (NEW) (*Effective October 1, 2006*) (a) A pharmacy may provide
112 pharmacy services to a health care facility or institution through the
113 use of an automated drug delivery system located within or outside of
114 the pharmacy, provided the pharmacy complies with this section and
115 the applicable provisions of section 2 of this act.

116 (b) Any drug stored in an automated drug delivery system for a
117 health care facility or institution shall be part of the inventory of the
118 pharmacy providing pharmacy services to that facility or institution,
119 and drugs dispensed from the automated drug delivery system shall
120 be considered to have been dispensed by that pharmacy.

121 (c) The pharmacy shall maintain records of the acquisition and
122 disposition of controlled drugs, as defined in section 21a-240 of the
123 general statutes, stored in the automated drug delivery system
124 separate from other pharmacy records.

125 (d) The pharmacy shall own and operate the automated drug
126 delivery system.

127 (e) The pharmacy shall provide training regarding the operation
128 and use of the automated drug delivery system to personnel of the
129 pharmacy and personnel of the health care facility or institution using
130 the automated drug delivery system.

131 (f) The operation of the automated drug delivery system shall be
132 under the supervision of a pharmacist. To qualify as a supervisor for
133 an automated drug delivery system, the pharmacist need not be
134 physically present at the site of the automated drug delivery system

135 and may supervise the system electronically.

136 (g) A pharmacist shall review the drugs contained within, and the
137 operation and maintenance of, the automated drug delivery system on
138 a monthly basis. Such review shall include a physical inspection of the
139 drugs in the automated drug delivery system, an inspection of the
140 automated drug delivery system machine for cleanliness and a review
141 of all transaction records in order to verify the security and
142 accountability of the system.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2006</i>	New section
Sec. 2	<i>October 1, 2006</i>	New section
Sec. 3	<i>October 1, 2006</i>	New section

Statement of Purpose:

To permit health care facilities and institutions licensed by the Department of Public Health to use automated drug delivery systems.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]